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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,171	07/18/2003	Rajeev S. Bhide	LD0310 NP	2727
23914	7590	05/21/2004	EXAMINER	
STEPHEN B. DAVIS			MCKENZIE, THOMAS C	
BRISTOL-MYERS SQUIBB COMPANY				
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PRINCETON, NJ 08543-4000			PAPER NUMBER	
1624				
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	10/623,171	Applicant(s)	BHIDE ET AL.
Examiner	Thomas McKenzie, Ph.D.	Art Unit	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 July 2003.
2a) This action is FINAL. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-26 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) Claim(s) 5,6,8,9 and 11-13 is/are allowed.
6) Claim(s) 1-4,7,10 and 14-26 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/22/03 & 3/11/04.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

DETAILED ACTION

1. This action is in response to an application filed on 7/18/03. There are twenty-three claims pending and twenty-three under consideration. Claims 1-6 are compound claims. Claims 7-13 are composition claims. Claims 14-26 are method of using claims. This is the first action on the merits. The application concerns some Pyrrolo[2,1-f][1,2,4]triazine compounds, compositions, and uses thereof.

Title

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: addition of the word "Pyrrolo[2,1-f][1,2,4]triazine" after "Novel".

Claim Objections

3. Claim 18 is objected to because of the following informalities: the phrase "claim 7" has run together. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 7, 10, and 14-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The word "prodrug" is indefinite. The issue on second paragraph is whether the structures of the claimed

compounds are clearly defined. Applicants' "prodrugs" are molecules whose structure lie outside the subject matter of formula (I), but upon metabolism in the body are converted to active compounds falling within the structural scope of formula (I). The claim describes the function intended but provides no specific structural guidance to what constitutes a "prodrug". Structural formulas, names, or both can accurately describe organic compounds, which are the subject matter of claim 1. Attempting to define means by function is not proper when the means can be clearly expressed in terms that are more precise. Applicants list the function that these prodrugs are to perform in the passage spanning line 32, page 12 to line 11, page 13 but offer no structural guidance as to which derivatives are intended.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 7, 10, and 14-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making salts of the claimed compounds, does not reasonably provide enablement for making prodrugs of the claimed compounds. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art of medicinal chemistry to use the invention. "The factors to be considered [in making an

enablement rejection] have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims”, *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. a) Finding a prodrug is an empirical exercise. Predicting if a certain ester of a claimed alcohol, for example, is in fact a prodrug, and produces the active compound metabolically, in man, at a therapeutic concentration and at a useful rate is filled with experimental uncertainty. Although attempts have been made to predict drug metabolism *de novo*, this is still an experimental science. For a compound to be a prodrug, it must meet three tests. It must itself be biologically inactive. It must be metabolized to a second substance in a human at a rate and to an extent to produce that second substance at a physiologically meaningful concentration. Thirdly, that second substance must be biologically active. Thus, determining whether a particular compound meets these three criteria in a clinical trial setting requires a large quantity of experimentation.

b) The direction concerning the prodrugs is found in the passage spanning line 32, page 12 to line 11, page 13. c) There is no working example of a prodrug of a compound the formula (I). d) The nature of the invention is clinical use of

compounds and the pharmacokinetic behavior of substances in the human body. e)

The state of the prodrug art is summarized by Wolff (Medicinal Chemistry). The table on the left side of page 976 outlines the research program to be undertaken to find a prodrug. The second paragraph in section 10 and the paragraph spanning pages 976-977 indicate the low expectation of success. In that paragraph the difficulties of extrapolating between species are further developed. Since, the prodrug concept is a pharmacokinetic issue, the lack of any standard pharmacokinetic protocol discussed in the last sentence of this paragraph is particularly relevant. Banker (Modern Pharmaceutics) in the first sentence, third paragraph on page 596 states that "extensive development must be undertaken" to find a prodrug. f) Wolff (Medicinal Chemistry) in the last paragraph on page 975 describes the artisans making Applicants' prodrugs as a collaborative team of synthetic pharmaceutical chemists and metabolism experts. All would have a Ph. D. degree and several years of industrial experience. g) It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). h) The breadth of the claims includes all of the hundreds of

thousands of compounds of formula of claim 1 as well as the presently unknown list potential prodrug derivatives embraced by the word "prodrug".

Thus, undue experimentation will be required to determine if any particular derivative is, in fact, a prodrug.

6. Claims 1-4, 7, 10, and 14-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making salts of the claimed compounds, does not reasonably provide enablement for making solvates and hydrates of the claimed compounds. The specification does not enable any person skilled in the art of synthetic organic chemistry to make the invention commensurate in scope with these claims. The factors to be considered in making an enablement rejection have been summarized above. In the present case the important factors leading to a conclusion of undue experimentation are the absence of any working example of a formed solvate, the lack of predictability in the art, and the broad scope of the claims.

c) There is no working example of any hydrate or solvate formed. The claims are drawn to solvates, yet the numerous examples presented all failed to produce a solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the

claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist." The same circumstance appears to be true here. There is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

g) The state of the art is that is not predictable whether solvates will form or what their composition will be. In the language of the physical chemist, a solvate of organic molecule is an interstitial solid solution. This phrase is defined in the second paragraph on page 358 of West (Solid State Chemistry). The solvent molecule is a species introduced into the crystal and no part of the organic host molecule is left out or replaced. In the first paragraph on page 365, West (Solid State Chemistry) says, "it is not usually possible to predict whether solid solutions will form, or if they do form what is their compositional extent". Thus, in the absence of experimentation one cannot predict if a particular solvent will solvate any particular crystal. One cannot predict the stoichiometry of the formed solvate, i.e. if one, two, or a half a molecule of solvent added per molecule of host. In the same paragraph on page 365 West (Solid State Chemistry) explains that it is

possible to make meta-stable non-equilibrium solvates, further clouding what Applicants mean by the word solvate. Compared with polymorphs, there is an additional degree of freedom to solvates, which means a different solvent or even the moisture of the air that might change the stable region of the solvate.

h) The breadth of the claims includes all of the hundreds of thousands of compounds of formula (I) as well as the presently unknown list of solvents embraced by the term "solvate". Thus, the scope is broad.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to make Applicants' invention.

7. Claims 18-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treating any proliferative disease, cancer, inflammation, autoimmune disease, or "diseases associated with signal transduction pathways operating through growth factor receptors". The specification does not enable any physician skilled in the art of medicine, to make

the invention commensurate in scope with these claims. The how to make requirement of the enablement statute, when applied to process claims, refers to operability and how to make the claimed process work. The factors to be considered in making an enablement rejection have been summarized above. The two issues are the correlation between clinical efficacy for disease treatment and Applicants' two *in vitro* enzyme assays as well as the wide breadth of the diseases to be treated.

a) Determining if any particular claimed compound would treat any particular claimed disease would require synthesis of the compound, formulation into a suitable dosage form, and subjecting it clinical trials with a number of fundamentally different diseases described below, or to testing them in an assay known to be correlated to clinical efficacy of such treatment. This is a large quantity of experimentation. b) The direction concerning treating the claimed diseases is found in the passage spanning line 21, page 13 to line 28, page 18, which merely states Applicants' intention to do so. Applicants describe formulations in the passage spanning line 29, page 18 to line 3, page 19. Doses required to practice their invention are described in lines 3-5, page 18. A 6,000-fold range of doses is recommended. Since no VEGFR-2 or FGFR-1 enzyme inhibitor has ever been used to treat any human disease, how is the skilled

physician to know what dose to use for each of these different diseases? There are two *in vitro* enzyme inhibition assay described in the passage spanning line 1, page 20 to line 10, page 21 with no data but it is unclear if these assays are correlated to treatment of the claimed diseases. c) There is no working example of treatment of any disease in man or animals. There is no working example of any formulation or dose that the average physician would require to practice Applicants' claimed therapies. d) The nature of the invention is clinical treatment of disease with inhibitors of the VEGFR-2 or FGFR-1 enzymes, which involves physiological activity. e) The state of the clinical arts in VEGFR-2 or FGFR-1 enzyme related diseases is provided by Eskens (Br J Cancer). Eskens (Br J Cancer) states in the conclusion, "until recently, these phase III trials, mostly done in patients with metastatic colorectal or breast cancer, all failed to show improved survival, and serious concern was growing as to whether we would ever be able to demonstrate the clinical efficacy of any of these exciting and promising agents". In the passage spanning pages 2-3, the reference teaches that no such enzyme inhibitor has demonstrated clinical efficacy. While Applicants may be now developing therapies with their compounds, even 2 years after Applicants effective filing date, highly skilled clinical scientists were unable to get VEGFR-2 or FGFR-1 enzyme inhibitors to work.

f) The artisan using Applicants invention would be a physician with a MD degree and several years of experience. g) It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

h) The scope of the claims involves all of the thousands of compounds of claim 1 as well as the thousand of diseases embraced by the terms proliferative disease, cancer, inflammation, and autoimmune disease, or the unknown list of "diseases associated with signal transduction pathways operating through growth factor receptors". Proliferative disease would include benign tumors, malignant tumors, polyps, lumps, lesions, other pre-cancerous conditions, psoriasis, leukemia, the hyper proliferation of the gastric epithelium caused by the *Helicobacter pylori* infection of ulcers, and the increased epidermal cell turnover induced by *Pityrosporum ovale* colonization, which causes dandruff. Cancer is just an umbrella term. Tumors vary from those so benign that they are never treated to those so virulent that all present therapy is useless. Inflammation is a process that can take place in virtually any part of the body. There is a vast range of forms that it can take, causes for the problem, and biochemical pathways that mediate the inflammatory reaction. There is no common mechanism by which all, or even

most, inflammations arise. Mediators include bradykinin, serotonin, C3a, C5a, histamine, leukotrienes, cytokines, and many, many others. Accordingly, treatments for inflammation are normally tailored to the particular type of inflammation present, as there is no, and there can be no “magic bullet” against inflammation generally. The “autoimmune diseases” are a process that can take place in virtually any part of the body. There is a vast range of forms that it can take, causes for the problem, and biochemical pathways that mediate the inflammatory reaction. There are hundreds of such diseases, which have fundamentally different mechanisms and different underlying causes. Thus, the scope of claims is extremely broad.

MPEP §2164.01(a) states, “A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).” That conclusion is clearly justified here and undue experimentation will be required to practice Applicants' invention.

Claim Rejections - 35 USC § 102

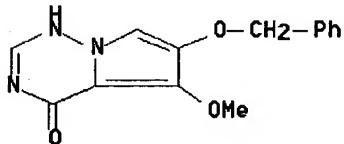
8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

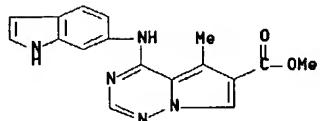
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Leftheris (WO 2002/40486 A2). The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131. The compound shown below fits formula (I) with Z = OH, R⁶ = R¹ = hydrogen, X = Y = O, R² = benzyl, and R³ = methyl. It has Registry Number 310444-95-2 and is found in lines 18-24, page 62 of the reference. The compound is shown in its keto tautomer form.



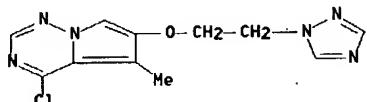
9. Claims 1, 2, 7, 10, and 14-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Hunt (WO 2000/71129 A1, cited by Applicants). The applied

reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. There are 30 compounds in this reference that teach Applicants' claims, two of which are shown below. The first compound shown below fits formula (I) with Z = NHR⁴², R⁴² = 1H-indol-6-y, n = 0, R⁴⁴ = R⁶ = R¹ = R² = hydrogen, X = CO₂, Y = absent, and R³ = methyl. It has Registry Number 310442-79-6 and is found in lines 9-17, page 61 of the reference. It is compound 66. It is also claimed in lines 25-26, page 114. Compositions are taught in claim 3 of the reference. Thus, the present claim 7 is taught. Compositions containing the anticancer agent tamoxifen are taught in claim 5 of the reference. Thus, the present claim 10 is taught. The claims 6-18 of the reference teach the same uses as presently claimed in claims 14-26.

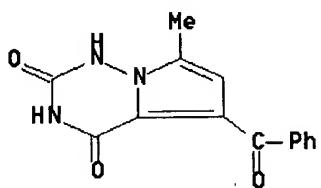


The second compound shown below fits formula (I) with Z = chlorine, R⁶ = R¹ = hydrogen, X = O, R² = ethyl substituted by 1H-1,2,4-triazol-1-yl, Y = absent,

and R³ = methyl. It has Registry Number 310444-87-2 and is found in the passage spanning line 32, page 91 to line 6, page 92 of the reference. The compound shown has an oxygen atom at position 6 of the pyrrolo[2,1-f][1,2,4]triazine ring. Thus, claim 2 is anticipated.

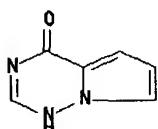


10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Migliara (Journal of Heterocyclic Chemistry). The compound shown below fits formula (I) with Z = OH, R⁶ = OR⁹, R² = R⁹ = hydrogen, R¹ = methyl, X = absent, Y = CO, and R³ = phenyl. It has Registry Number 71971-30-7 and is found in Scheme 1, page 833 of the reference. The compound drawn below and in the reference is in its keto tautomer form. It is compound 7d. Synthesis is described in the third paragraph, column 2, page 834. See also compounds 7c and 8.

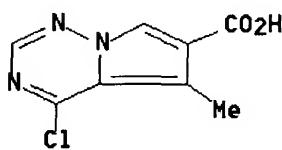


11. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Patil (Journal of Heterocyclic Chemistry). The compound shown below fits formula (I) with Z = OH, R¹ = R⁶ = R² = R³ = hydrogen, and X = Y = absent. It has Registry

Number 159326-71-3 and is found in Scheme 2, page 782 of the reference. The compound is drawn in its keto tautomer form. It is called compound 8. Synthesis is found in the first complete paragraph, column 2, page 784. See also compound 12.



12. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Godfrey ('357). The compound shown below fits formula (I) with Z = chlorine, R¹ = R⁶ = R² = hydrogen, and X = CO₂, Y = absent, and R³ = methyl. It has Registry Number 607738-99-8 and is found in lines 1-15, column 36 of the reference.



13. Quintela (Tetrahedron), Ohtani (WO 2001/014378 A1), Leftheris (WO 2002/040486 A2), Lombardo (US 2003/0232832 A1), Dyckman (US 2003/0232831 A1), Dyckman (US 2004/0082582 A1), and Mastalerz (US 2003/0186983 A1) are all cumulative with the rejections made above but are made of record.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 7, 10, 20, and 24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 12, and 16 of copending Application No. 09/573,829. Although the conflicting claims are not identical, they are not patentably distinct from each other because this is the US equivalent of Hunt (WO 2000/71129 A1, cited by Applicants) discussed above. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

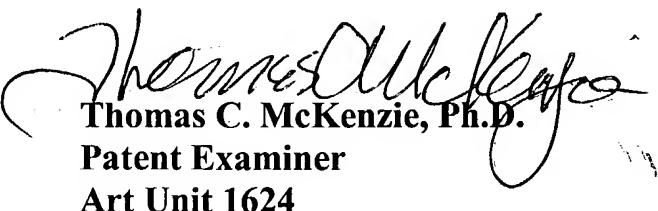
Allowable Subject Matter

15. Claims 5, 6, 8, 9, and 11-13 are allowed.

Conclusion

16. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

17. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (703) 872-9306. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact James O. Wilson, acting SPE of Art Unit 1624, at (571)-272-0661.


Thomas C. McKenzie, Ph.D.
Patent Examiner
Art Unit 1624